Prescribing Information: Fyremadel® (ganirelix acetate) 0.25 mg/0.5 ml solution for injection in pre-filled syringe.

Please consult the full Summary of Product Characteristics before prescribing.

Name of Product: Fyremadel® 0.25 mg/0.5 ml solution for injection in pre-filled syringe. **Composition:** Each pre-filled syringe contains 0.25 mg of ganirelix (as acetate) in 0.5 ml aqueous solution. **Indication:** Fyremadel® is indicated for the prevention of premature luteinising hormone (LH) surges in women undergoing controlled ovarian hyperstimulation (COH) for assisted reproduction techniques (ART). **Dosage and administration:** Fyremadel® (0.25 mg) should be injected subcutaneously once daily, starting on day 5 or day 6 following the administration of FSH or corifollitropin alfa. Fyremadel® and FSH should be administered approximately at the same time. However, the preparations should not be mixed, and different injection sites are to be used. Daily treatment with Fyremadel® should be continued up to the day that sufficient follicles of adequate size are present. Final maturation of follicles can be induced by administering human chorionic gonadotrophin (hCG). Because of the half-life of Fyremadel®, the time between two Fyremadel® injections as well as the time between the last Fyremadel® injection and the hCG injection should not exceed 30 hours. **Method of administration**: Fyremadel® should be administered subcutaneously, preferably in the upper leg. The injection site should be varied to prevent lipoatrophy. **Contraindications:** Fyremadel® should not be used in individuals with hypersensitivity to the active substance or to any of the excipients (glacial Acetic acid, mannitol, sodium hydroxide) and with hypersensitivity to gonadotrophin-releasing hormone (GnRH) or any other GnRH analogue, or with moderate or severe renal or hepatic impairment. Pregnancy or breast feeding. **Special Warnings and Precautions:** Hypersensitivity reaction**:** Special care should be taken in women with signs and symptoms of active allergic conditions. Hypersensitivity reactions (both generalised and local) have been reported with Fyremadel®, as early as with the first dose.These events include anaphylaxis (including anaphylactic shock) angioedema and urticaria. If a hypersensitivity reaction is suspected, Fyremadel® should be discontinued and appropriate treatment administered. Fyremadel® treatment is not advised in women with severe allergic conditions. Latex allergy: The needle cover contains dry natural rubber/latex which comes into contact with the needle and may cause allergic reactions. Ovarian hyperstimulation syndrome (OHSS) may occur during or following ovarian stimulation and must be considered an intrinsic risk of gonadotrophin stimulation. Since infertile women undergoing assisted reproduction, and particularly in vitro fertilisation often have tubal abnormalities the incidence of ectopic pregnancies might be increased. Early ultrasound confirmation that a pregnancy is intrauterine is therefore important. The incidence of congenital malformations after ART may be higher than after spontaneous conceptions. In clinical studies investigating more than 1000 new-borns it has been demonstrated that the incidence of congenital malformations in children born after COH treatment using Fyremadel® is comparable with that reported after COH treatment using a GnRH agonist. The safety and efficacy of Fyremadel® have not been established in women weighing less than 50 kg or more than 90 kg. No drug interaction studies have been performed with Fyremadel®. **Side effects:** Very common: Fyremadel® may cause a local skin reaction at the site of injection (predominantly redness, with or without swelling). The local reactions generally disappear within 4 hours after administration. Uncommon: headache, malaise, nausea. Very rare: Hypersensitivity reactions**. Prescribers should consult the summary of product characteristics in relation to other adverse reactions**. **Special precautions for storage:** This medicinal product does not require any special storage conditions. **Presentation:** Pre-filled syringes containing 0.5 ml of sterile, ready for use, aqueous solution closed with the grey rubber plunger stopper and polypropylene plunger rod. Injection needles (27 G) affixed to the barrel and provided with grey elastomeric needle shield and polypropylene rigid needle shield. The needle cover contains dry natural rubber/latex. Supplied in cartons containing 1 or 5 pre-filled syringes. **Marketing Authorisation Number:** PL 31750/0055 **Marketing Authorisation Holder:** Sun Pharmaceutical Industries Europe B.V. Polarisavenue 87, 2132 JH Hoofddorp, The Netherlands. **Legal category:** POM **Basic NHS price:** Fyremadel® x 1 pre-filled syringe £19.35, Fyremadel® x 5 pre-filled syringes £96.75 **Date of preparation:** May 2020 Fyremadel® is a registered trademark. **PI Job Code:** UK-FYR-2000002.

Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.**

Adverse events should also be reported to Sun Pharmaceuticals Industries Europe B.V.

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